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NOTICE OF ALLOWANCE AND FEE(S) DUE

30565 7590 12/04/2009

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

DATE MAILED: 12/04/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,343

03/26/2004

William A. Cook

3433-492

1552

TITLE OF INVENTION: GRAFT PROSTHESIS, MATERIALS AND METHODS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	03/04/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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30565 7590 12/04/2009

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

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hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,343 03/26/2004 William A. Cook 3433-492 1552

TITLE OF INVENTION: GRAFT PROSTHESIS, MATERIALS AND METHODS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 03/04/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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PREBILIC, PAUL B 3774 623-023750

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,343	03/26/2004	William A. Cook	3433-492	1552
30565	7590	12/04/2009	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3774	
DATE MAILED: 12/04/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 447 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 447 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/811,343	COOK ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilio	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the information disclosure statement filed November 30, 2009.
2. ☒ The allowed claim(s) is/are 27-46, 48-54 and 64-66.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>11/30/2009</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
|--|---|

/Paul B. Prebilio/
Primary Examiner, Art Unit 3774

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kenneth Gandy on November 25, 2009.

The application has been amended as follows:

Claims 1-26. (Cancelled)

27. (Previously Presented) A method for obtaining a collagen-based matrix comprising submucosa from a submucosa tissue source comprising:

treating a submucosa tissue source that includes submucosa and attached tunica muscularis tissue with an oxidizing disinfecting agent to provide a disinfected submucosa tissue source; and

removing the collagen-based matrix comprising submucosa from the disinfected submucosa tissue source, said removing including separating amounts of the attached tunica muscularis tissue from the submucosa.

28. (Original) The method of claim 27, wherein the submucosa tissue source is from an alimentary tract of a mammal.

29. (Original) The method of claim 28, wherein the mammal is a pig.

30. (Original) The method of claim 29, wherein the submucosa tissue source is from the small intestine of a pig.

31. (Previously Presented) The method of claim 27, wherein said treating includes contacting the submucosa tissue source with a liquid medium containing the disinfecting agent. the disinfecting agent is an oxidizing agent.

32. (Original) The method of claim 27, wherein the disinfecting agent is a peroxy compound.

33. (Original) The method of claim 32, wherein the disinfecting agent is an organic peroxy compound.

34. (Original) The method of claim 33, wherein the disinfecting agent is a peracid.

35. (Original) The method of claim 34, wherein the peracid is selected from the group consisting of peracetic acid, perpropionic acid and perbenzoic acid.

36. (Original) The method of claim 35, wherein the peracid is peracetic acid.

37. (Original) The method of claim 34, wherein said treating includes treating the submucosa tissue source with a medium containing an alcohol and the peracid.

38. (Original) The method of claim 37, wherein the alcohol has one to about six carbon atoms.

39. (Original) The method of claim 38, wherein the alcohol is selected from the group consisting of ethanol, propanols, and butanols.

40. (Original) The method of claim 39, wherein the alcohol is ethanol.

41. (Original) The method of claim 40, wherein the medium is an aqueous ethanol solution containing from about 0.1% to about 0.3% by volume peracetic acid.

42. (Original) The method of claim 34, wherein said treating includes treating the submucosa tissue source with a medium containing the peracid and having a pH of about 2 to about 6.

43. (Original) The method of claim 42, wherein the medium has a pH of about 2 to about 4.

44. (Original) The method of claim 43, wherein the peracid is peracetic acid, and the medium contains about 0.1% to about 0.3% by volume of peracetic acid.

45. (Currently Amended) A method for obtaining a collagen-based matrix comprising submucosa from a submucosa tissue source, comprising:

providing a submucosa tissue source that includes submucosa and attached tunica muscularis tissue, ~~which has been treated with an oxidizing disinfecting agent;~~
treating said submucosa tissue source with a sufficient amount of oxidizing disinfecting agent to disinfect said submucosa tissue source; and

removing the collagen-based matrix comprising submucosa from said treated submucosa tissue source, said removing including separating amounts of the attached tunica muscularis tissue from the submucosa.

46. (Original) The method of claim 45, wherein said submucosa tissue source is from a small intestine.

47. (Cancelled)

48. (Previously Presented) The method of claim 46, wherein said treating includes contacting the submucosa tissue source with an aqueous medium containing the oxidizing agent.

49. (Currently Amended) The method of claim ~~[[47]]~~ 45, wherein said treating includes contacting the submucosa tissue source with an aqueous medium containing a peroxy compound.

50. (Original) The method of claim 49, wherein the peroxy compound is a peracid.

51. (Original) The method of claim 50, wherein the peracid is peracetic acid.

52. (Original) The method of claim 51, wherein the medium comprises an alcohol.

53. (Original) The method of claim 52, wherein the alcohol is ethanol.

54. (Original) The method of claim 51, wherein the small intestine is from a pig.

Claims 55-63. (Cancelled)

64. (Previously Presented) A method for obtaining a collagen- containing matrix from a submucosa tissue source, comprising:

providing a submucosa tissue source including submucosa tissue and tunica muscularis tissue attached to the submucosa tissue; wherein the submucosa tissue source is from urinary tract tissue;

separating the tunica muscularis tissue from the submucosa tissue;

recovering a collagen-containing matrix including the submucosa tissue separated from the tunica muscularis tissue;

wherein said collagen-containing matrix comprises the submucosa tissue and lamina propria tissue;

wherein said collagen-containing matrix exhibits an endotoxin level of less than 1 endotoxin unit per gram;

wherein said collagen-containing matrix exhibits a bioburden of less than 0.5 colony forming units per gram;

wherein said collagen-containing matrix retains glycosaminoglycans, glycoproteins, proteoglycans and growth factors from said tissue source, and said growth factors include basic fibroblast growth factor; and

wherein said collagen-containing matrix exhibits a capacity to induce angiogenesis.

65. (Previously Presented) The method of claim 64, also comprising contacting the submucosa tissue with an aqueous solution containing peracetic acid.

66. (Previously Presented) The method of claim 64, wherein the submucosa tissue source is porcine.

Claims 67-70. (Cancelled)

The following is an examiner's statement of reasons for allowance:

Upon review of the information disclosure statement filed November 30, 2009, the Examiner thought that Probst et al (British Journal of Urology) was of particular interest. On page 506, a method of preparing BAMG is disclosed that utilizes sodium azide to treat the bladder tissue. Upon further investigation, it was determined that sodium azide can act as a disinfectant but would act as a reducing agent not an oxidizing agent or oxidizing disinfectant as called for in the present claim language. For

Art Unit: 3774

this reason, the claims are not met in this regard. Furthermore, since the present claims are drawn to an unpredictable art, the Examiner asserts that it would not have been obvious to substitute an oxidizing disinfecting agent for the reducing disinfecting agent of Probst because the result would not be predictable to an ordinary artisan.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774